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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,419	10/01/2003	Hirotooshi Adachi	MUR-022-USA-P	5125

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TOWNSEND & BANTA
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Washington, DC 20004

EXAMINER

DI NOLA BARON, LILIANA

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 03/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/674,419	ADACHI ET AL.	
	Examiner	Art Unit	
	Liliana Di Nola-Baron	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/651,272.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date, _____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 23-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claims 23-25 recite the limitation "The device structure for iontophoresis according to claim 6" in line 1. There is insufficient antecedent basis for this limitation in the claims, since claim 6 has been cancelled by Applicant's preliminary amendment.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 17-25 are rejected under 35 U.S.C. 102(e) as being anticipated by Sun et al. (U.S. Patent 6,678,554).

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The patent provides an electrotransport, including iontophoresis, delivery system comprising a reservoir containing an ionic drug and an electrode within a low electrolyte aqueous solution and an electrode within the reservoir (See col. 1, lines 58-67 and col. 2, line 49 to col. 3, line 6). The patent includes cationic and anionic agents among the active agents, which may be delivered by the system of the invention (See col. 5, line 18 to col. 6, line 4) and teaches that buffering agents, such as polymers with acidic functional groups or basic functional groups are placed in the fluid reservoir (See col. 12, lines 24-65). The low electrolyte aqueous solution disclosed by the patent is an electrically conductive layer, as claimed by Applicant. With regard to the limitation in the claims, that the polymer has a polarity selected for controlling pH variations, the patent teaches that polymers, such as Eudragit S or Eudragit E, maintain the pH of the electrode medium (See col. 12, lines 38-65). Thus the patent anticipates claims 17, 18 and 22.

With regard to claims 19-21 and 23-25, the patent discloses copolymers of methacrylic acid and methacrylate, such as Eudragit L and S, as anionic polymers, and includes polymers with amine groups, such as copolymers of dimethylaminoethyl methacrylate and methacrylic acid esters (Eudragit E), among the cationic polymers with basic functional groups (See col. 12, lines 24-65).

The compositions disclosed by Sun et al. meet the limitations of claims 17-25 of the instant application, as the patent discloses a system for iontophoresis comprising an electrically conductive layer comprising an ionized active ingredient and a water-swellaable polymer. Thus, the patent anticipates the claimed invention.

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6. Claims 17-25 are rejected under 35 U.S.C. 102(e) as being anticipated by Suzuki et al. (U.S. Patent 6,416,503).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Suzuki et al. discloses a system for iontophoresis, comprising a cationized drug, an anode and cathode and film bases, such as Eudragit E, Eudragit L and Eudragit S (See col. 5, line 9 to col. 12, line 23). The pH adjusting function claimed by Applicant is inherent.

The compositions disclosed by Suzuki et al. meet the limitations of claims 17-25 of the instant application, as they contemplate a composition comprising a ionized active ingredient and a water-swelling polymer. Thus, the patent anticipates the claimed invention.

7. Claims 17-25 are rejected under 35 U.S.C. 102(e) as being anticipated by Iga et al. (U.S. Patent 6,322,550).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the

inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Iga et al. provides a device for transdermal administration of a GP Iib/IIIa antagonist by iontophoresis, comprising a conductive layer containing a hydrophilic gel (See col. 6, lines 40-64). Iga et al. teaches that the gel comprises vinyl resins, aminoacrylmethacrylate (Eudragit E), methacrylic acid copolymers (Eudragit L, Eudragit S), amino acids and their salts (See col. 7, line 2 to col. 9, line 67). The pH adjusting function claimed by Applicant is inherent. The compositions disclosed by Iga et al. meet the limitations of claims 17-25 of the instant application, as they contemplate a composition comprising a ionized active ingredient and a water-swelling polymer, and a conductive layer comprising said composition. Thus, Iga et al. anticipates the claimed invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Liliana Di Nola-Baron whose telephone number is 571-272-0592. The examiner can normally be reached on Monday through Thursday, 8:30AM-7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached at 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.


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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



March 4, 2004



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SUPERVISORY PATENT EXAMINER
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